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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 10/801,648   | 03/17/2004  | Hsiang-Fu Kung       | V9661.0074                  | 2232             |
| 32172  | 7590        | 12/15/2006           |                             |                  |
| DICKSTEIN SHAPIRO LLP<br>1177 AVENUE OF THE AMERICAS (6TH AVENUE)<br>NEW YORK, NY 10036-2714 |             |                      |                             |                  |
|  |             |                      | EXAMINER<br>KELLY, ROBERT M |                  |
|  |             |                      | ART UNIT<br>1633            | PAPER NUMBER     |

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |                 |              |  |
|---|-----------------|--------------|--|
| <b>Advisory Action</b><br><b>Before the Filing of an Appeal Brief</b> | Application No. | Applicant(s) |  |
|   | 10/801,648      | KUNG ET AL.  |  |
|   | Examiner        | Art Unit     |  |
|   | Robert M. Kelly | 1633         |  |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: None
- Claim(s) objected to: 13-16, 23-26
- Claim(s) rejected: 13-16, 23-26, 29-33, 35-47
- Claim(s) withdrawn from consideration: 1-9, 17-22, 27-28, 34

*RMK 12/11/06*

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_

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 AU1633

Continuation of 3. NOTE: Applicants claims encompass various limitations not previously claimed. For Example, Claim 13 now encompasses particular diseases and disorders, as well as amelioration of disorder. The scope of such limitations was not previously considered and requires considerations for comprising new matter, given the specific disorders, amelioration and administration methods.

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicant's reply, if it were entered, would overcome the following: the objection to the specification for containing a table of contents; the objections to claims 13-16 and 23-26; the rejections for clarity under 35 USC 112, of claims 13-16, 23-26, 29-33, 35-47; the rejections of claims 13-16, 23-26, 29-33, and 35-40 for comprising new matter; the written description for the scope of administration, on claims 13-16, 23, 25-26, and 29-47; and the rejections and/or objections to any proposed-cancelled claim.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's proposal to amend the specification by simply replacing the amended sequences with the old ones is not allowed, because all amendments to the specification must be accompanied by a properly marked amendment sheet, computer disc, and sworn statement (MPEP 714). The enablement rejection would remain as it stands, being applied to all the proposed claims, as they encompass the various aspects already addressed. Applicant's broad argument that such treatments are reasonably predictable are not given weight. Attorney argument does not supplant the need for specific demonstrations that the facts and/or logic of the Examiner is incorrect.